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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,816	08/27/2001	Elliott Farber	14358-314	2827

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EXAMINER

SHARAREH, SHAHNAMEH J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,816

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 20-21, 24, 26, 28, 30, 32, 34, 35, 38-39, 42-44, 48, 56, 59, 63, 66, 79, 73 is/are rejected.
- 7) ☒ Claim(s) 49-55, 60-62, 67-69 and 74-76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-19,22,23,25,27,29,31,33,36,37,40,41,45-47,57,58,64,65,71 and 72.

DETAILED ACTION

1. Amendment filed on October 03, 2003 has been entered. Claims 1-76 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

Election/Restrictions

2. Applicant made the election of species of Applicators having beeswax and an anionic emulsifier as the emulsifier system in Paper No. 8. Claims 1-11, 20-21, 24,26, 28, 30, 32, 34, 35, 38-39, 42-44, 48-56, 59-63, 66-70, 73-76 were declared to be towards the elected species and thus they are under consideration.

Claims 12-19, 22-23, 25, 27, 29, 31, 33, 36-37, 40-41, 45-47, 57-58, 64-65, 71-72 were withdrawn from further consideration because they were not directed towards the elected species.

3. Applicant's request to reconsider some of the withdrawn claims was noted and considered (see Amendment at page 23-24). However, said claims are not rejoined and are not being considered because they are not of the same scope as those commonly owned by the Applicant. During the telephonic interview conducted in August 18, 2003 and contrary to Applicant's assertion at page 24 of the Amendment, Examiner agreed to consider the withdrawn claims if the scope of the patented claims are the same; not similar (emphasis added), as those instantly presented in claims 12-19, 22-23, 25, 27, 29, 31, 33, 36-37, 40-41, 45-47, 57-58, 64-65, 71-72. Since the claims allowed and commonly owned by Applicant in US Patent 6,281,236 ('236) do not mirror the scope of

the pending withdrawn claims, Applicant's request to rejoin and reconsider the withdrawn claims at this time is denied.

Please note that the patented claims 1 and 8 possess different limitations as the instantly withdrawn claims. For example, the patented claim 8 of '236, which is the closest in scope to the instant withdrawn claims, requires the oil-in-water composition to contain at least an anionic emulsifier and possess a pH of 4.5-5.8 for allantoin to be stable for at least 90 days at 40 deg Celsius. Respectively, the patented claim 1 of '236 requires beeswax in combination with an anionic emulsifier as an essential component of the oil-in-water emulsion for allowing the allantoin to stay stable for at least 90 days at 40 deg Celsius at a pH of 4.5-5.8. The instant withdrawn claims do not have such limitations. Therefore, Applicant's request for reconsideration of the withdrawn claims is denied.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-5, 20, 24, 26, 28, 30, 34-35, 42-44, 48, 63, 66, 70, 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier I), and Venkitaraman et al US Patent 5,871,762.

5. Claims 1-11, 20-21, 24, 26, 28, 30, 32, 34-35, 38-39, 42-44, 48, 56, 59, 63, 66, 70, 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US

Patent 4,767,618 (Grollier I), and Venkitaraman et al US Patent 5,871,762, as applied to claims 1-5, 20, 24, 26, 28, 30, 34-35, 42-44, 48, 63, 66, 70, 73 and further in view of Grollier US Patent 4,880,621 (Grollier II), Chodosh US Patent 5,661,170, Briggs et al US Patent 5,871,754, and Yamanaka et al US Patent 5,176,916, as applied to claim 6-11, 21, 32, 38-39, 56, 59.

6. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant's essentially argues to issues. First, the primary reference, Kuroda, does not teach stability of allantoin at concentrations higher than 0.4%. Second, the secondary references, Grollier references, do not teach the instantly claimed pH values.

7. Such arguments are not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, it is the combined teachings of the references that render the instant claims obvious.

8. As the initial matter, Kuroda teaches stability of allantoin in pH values overlapping the instantly claimed pH values. See page 6, last line of Kuroda where it states that it is suitable to adjust the pH into the range of 4-5.5.

9. Second, there are no teachings away in Kuroda to discourage increasing or decreasing the concentrations of allantoin in his compositions. Therefore, it would have been well within the ordinary skill level of an artisan to optimize allantoin's concentrations to determine the upper or lower limits of allantoin concentrations for

stability purposes. It has been reasoned that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33 (CCPA 1937). *In re Russell*, 439 F.2d 1228, 169 U.S.P.Q. 426 (CCPA 1971). Thus, absence of showing unexpected results optimizing ranges or concentrations of allantoin to above 0.4% would have been obvious and would have been achieved by routine experimentation.

10. Third, the teachings of Grollier are merely employed to supplement the teachings of Kurado for the additional ingredients that can be incorporated into Kurado's compositions. The fact that Grollier teaches that various suitable ingredients such as beeswax, herbal extracts, and preservative agents can be combined in a topical oil-in-water emulsion with allantoin provides ample expectation of success for combining said ingredients in Kurado's compositions. Therefore, Grollier's failure to explicitly recite the instantly claimed pH ranges is immaterial.

11. Nevertheless, despite Applicant's assertion, Grollier references in numerous places encourage the use of pH modifier for formulation a suitable topical utility. See for example, Grollier I at col 6, line 61-53 and Grollier II at col 5, lines 10-15, encouraging the use of pH modifiers, perfumes, preservative agents, and sequestrants in his oil-in-water emulsions.

12. For the reasons set forth above and the previous Office Action, all limitations of the instantly claimed inventions are described by the combined teachings of the references. Thus, claims stand rejected.

Claim Objections

Claims 49-55, 60-62, 67-69, 74-76 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 49-55, 60-62, 67-69, 74-76, are free of art, because the recited concentration of each component of within the emulsion is not taught in the prior art and thus there is no expectation of success in the art to render such combination of components obvious with the allantoin staying stable for 90 days at the claimed pH ranges.

Conclusion

14. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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